DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action and Applicant's Arguments/Remarks, all filed 03/11/08 is acknowledged.

Applicant has overcome the 35 U.S.C. §112, first paragraph rejection of claims 1 and 15 by virtue of the persuasive remarks.

Claims 1 and 9-16 are pending in this action. No amendments to the claims have been made herein. Claims 2-8 have previously been cancelled. Claims 1 and 9-16 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlisle (U.S. Pat. No. 3,824,996) in view of Dyer *et al.* (U.S. Pat. No. 5,899,893) and further in view of Bernardin *et al.* (U.S. Pat. No. 5,124,197).

<>The instant invention is drawn to a method of treating an acute wound using a wound dressing as a substitute for a biological dressing or skin graft comprising the steps of:

a) applying the wound dressing to the wound; and

b) allowing the wound dressing to adhere to the wound and be left in place for a period of time until after epithelial outgrowth and vertical wicking into the dressing occur, wherein the wound dressing comprises highly absorbent fibers.

<>The instant invention is also drawn to a method of treating an acute wound using a wound dressing comprising highly absorbent fibers that can absorb at least 25 g/g of deionized water comprising the steps of:

a) applying the wound dressing to the wound;

b) allowing the wound dressing to become adhered to the wound;

c) leaving the dressing in place until it dries out to form a crust; and

d) removing the dressing once the wound has healed.

<>The instant invention is also drawn to a method for substituting a wound dressing comprising highly absorbent fibers that can absorb at least 25 g/g of deionized water for a biological dressing comprising the steps of:

a) applying the wound dressing to a wound that would otherwise be treated using a biological dressing; and

b) allowing the wound dressing to adhere to the wound and be left in place for a period of time until after epithelial outgrowth and vertical wicking into the dressing occur, wherein the wound dressing comprises highly absorbent fibers.

Carlisle ('996) teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract).

According to Carlisle, the dressings have a finely porous, highly dense fibrous construction which provides the dual advantages of dispersing absorbed exudates to a low interlayer adhesion level, and preventing healing tissues from becoming entangled with the

dressing's fibrous material (col. 3, lines 53-67). Carlisle teaches the significance of speed of absorption, direction of absorption and the length of wicking (col. 4, lines 1-14). The chart at column 4 demonstrates that the dressing of Carlisle absorbs fluid steadily and continuously (i.e., wicking) (see col. 4, lines 15-55).

Carlisle teaches that the dressing layer materials can absorb distilled water *vertically* against gravity continuously for more than 5 hours (see claim 4). Carlisle also teaches that the dressing, when affixed and held in place with retaining material, adapts to exert relatively even pressure on the wound surface which tends to improve the quality of the repair tissue formed during healing (claim 17).

The wound dressings can be applied to wounds, such as burns (col. 2, lines 63-67).

Suitable dressing materials taught includes hard and soft wood pulp (col. 5, lines 19-22) and fibrous dense cellulose materials (see claims 1, 5, 6, 18).

With regards to the claim limitation 'for a period of time until after epithelial outgrowth and vertical wicking occur' recited in instant claim 1, the Examiner notes that this limitation does not impart patentable weight to the claims. The limitation is relative in terms of the time required in which epithelial outgrowth and/or vertical wicking occurs since the limitation fails to set forth any specific time or duration parameters that is required for epithelial outgrowth and vertical wicking to occur.h regards to the amount of water (25 g/g) absorbed claimed in claims 12-15, Carlisle does not teach absorbing at least 25 g/g of deionized water. However, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art,

it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts through routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. The particular method of treating an acute wound using a wound dressing and applying the wound dressing to the wound would be obvious in view of the disclosure of Carlisle. Carlisle clearly teaches highly absorbent pressure dressings for wounds, such as burns, constructed from cellulosic, fibrous material, whereby the dressings are applied and affixed to curved surfaces of the human body.

In any event, **Dyer *et al.*** ('893) are relied upon for their teaching of absorbent articles, such as wound dressings, having a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g. Particularly preferred foam absorbents will wick at least about 45 g/g. The foam absorbents of the invention wick a high capacity of the test fluid to a particular height at equilibrium (see reference column 1, lines 11-19); (col. 2, line 45); (col. 7, lines 41-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the absorbent articles of Dyer *et al.* within the teachings of Carlisle. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Dyer *et al.* teach absorbent articles, particularly wound dressings and teach that their absorbent articles are able to wick at a high capacity at equilibrium, such as a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g and even at least about 45 g/g. The expected result would be a highly absorbent wound dressing that is beneficially used for the treatment of acute wounds.

Bernardin *et al.* ('197) are relied upon for the teaching of an absorbent web formed from inflated cellulose fibers whereby the web possesses improved vertical wicking properties (see col. 1, line 6 – col. 2, line 30); (col. 3, lines 16-28) and Abstract. The absorbent webs are suitable for use in forming absorbent products, such as dressings, incontinence products, feminine pads and the like (col. 6, lines 41-46). Suitable fibers used in the invention include natural fibers, such as wood fibers, cotton linters and cotton staple (col. 3, lines 46-58).

Bernardin *et al.* teach that as a general rule, the vertical wicking properties of a web will be considered improved when the web exhibits at least about a 20 percent increase in initial vertical wicking rate, vertical wicking capacity (at 15 or 30 minutes) or vertical fluid distribution (at a distance between nine and eighteen cm) when compared to a similar web (col. 4, lines 36-52).

Bernardin *et al.* teach that the improved vertical wicking properties of the webs allows fluid to be vertically wicked from one particular area of the web to another remote location on the web. The absorbent web is able to transport fluid from one location on the web to another location on the web, based on the improved vertical wicking properties (col. 7, lines 8-40).

It would have been obvious to incorporate the absorbent cellulose fibers that exhibit improved wicking properties within the highly absorbent pressure dressing of Carlisle. One of ordinary skill in the art would do so with a reasonable expectation of success because Bernardin *et al.* teach an absorbent web made of cellulosic fibers, for use in absorbent products such as dressings and teach that the vertical wicking properties allows the absorbent web to transport fluid from one location on the web to another location on the web, thus increasing the absorbent capacity of the absorbent web.

Given the teachings of Carlisle, Dyer *et al.* and Bernardin *et al.* delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 03/11/08 have been fully considered, and were found to be partially persuasive.

- **35 U.S.C. §112, first paragraph Rejection:**

Applicant argued, "Support for this concept (as in "allowing the wound dressing to adhere to the wound and be left in place for a period of time *until after* epithelial outgrowth and vertical wicking into the dressing occur") is found throughout the specification. See, for example, pages 3 and 5. Additionally, see Example 2, where the dressing could be easily removed once re-epithelialization was complete. Then, cryosections of the dressing showed that the dressing fibers had swelled suggesting the dressing had vertically wicked the wound exudate away from the wound."

This argument has been considered and was found persuasive. Accordingly, the 35 U.S.C. §112, first paragraph rejection of claims 1 and 15 has been withdrawn.

- **35 U.S.C. §103(a) Rejection of claims 1 and 9-16 over Carlisle (U.S. Pat. No. 3,824,996) in view of Dyer et al. (U.S. Pat. No. 5,899,893) and Bernardin et al. (U.S. Pat. No. 5,124,197):**

Applicant argued, "Carlisle is concerned with pressure dressings. According to Carlisle, pressure dressings are fundamental in the preparation of wounds for skin grafting. Carlisle does not consider his dressing as a substitute for a biological dressing, but rather as a preparation for it. Carlisle, would not, therefore, motivate the person of ordinary skill to use a fibrous dressing as a substitute for a biological dressing. Further, dressings of Carlisle are dense, laminar dressings that wick laterally and bar the movement of exudates perpendicular to the plane of the dressing."

Applicant's arguments have been considered, but were not found persuasive. Carlisle teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract). The fact that Applicants dressing can be used as a substitute for biological dressings does not provide for a patentable distinction over the wound dressings of the art. The Carlisle wound dressings are formed of the same materials as that of Applicant's dressing.

Applicant argued, "Carlisle does not teach that the dressing is left in place or vertical wicking and does not suggest that there would be any advantage in vertical wicking".

This argument was not persuasive. Carlisle recognizes that their wound dressing can be left on the skin for extended periods of time, such as two or more weeks, if desired (col. 3, lines 54-67). Applicants desire that their wound dressing is left in place, however this step does not impart any unexpected results or a patentable distinction over the Carlisle reference teachings. With regard to vertical wicking, Carlisle teach that speed and direction of absorption and length of wicking is important for their dressing. While vertical wicking is not explicitly discussed, the

reference of Bernardin et al. is relied upon for the teaching of absorbent webs formed from cellulose fibers, used in dressings, whereby the absorbent webs demonstrate improved vertical wicking properties. Thus, this limitation has been met.

Applicant argued, "The Action relies on Dyer, et al. to supply the deficiencies of Carlisle. However, there must be a suggestion in Carlisle to do so. Carlisle is concerned with pressure dressings that have limited compressibility. The dressing material of Dyer is foam, and it is well known that foams are highly compressible. Thus, a person having ordinary skill in the art would not substitute the foam of Dyer et al. for the lamellar dressing of Carlisle in order to improve the Carlisle dressing. Dyer does not demonstrate vertical wicking."

These arguments were not found persuasive. While Carlisle teach lateral wicking, rather than vertical wicking, Dyer et al. are relied upon to demonstrate that it is well known in the art to employ absorbent articles, such as wound dressings that have vertical wicking capability of at least about 30 g/g. Applicant's argument that "Carlisle teaches limited compressibility pressure dressings whereas Dyer is directed to a highly compressible foam" was not persuasive since both references are directed to highly absorbent articles used for wound dressing applications. Thus, this is a sufficient criterion to combine the references. Applicants stated that the "wicking in Dyer is the wicking of a vertically held strip of a test material against gravity." Thus, the Examiner relies on the tertiary reference of Bernardin et al. Bernardin et al. is relied upon for the teaching of absorbent webs formed from cellulose fibers, used in dressings, whereby the absorbent webs demonstrate improved vertical wicking properties. The improved vertical wicking properties allow for transport of fluid from one location on the web to another remote location, thus providing for increased absorbent capacity of the absorbent web.

Applicant argued, "Bernardin does not teach vertical wicking in the same sense as it is used in Applicant's claims to mean wicking in a direction perpendicular to the plane of the dressing."

This argument was not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., vertical wicking intended for wicking in a direction perpendicular to the plane of the dressing) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The claims, as presently recited remain generic enough to read on the combined teachings of the art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

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